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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,838	03/30/2004	Mohan Gopalkrishna Kulkarni	U 015267-9	3117
7590 11/04/2004			EXAMINER	
William R. Evans Ladas & Parry 26 West 61 Street New York, NY 10023			ZEMEL, IRINA SOPHIA	
			ART UNIT	PAPER NUMBER
			1711	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/812,838

Applicant(s)

KULKARNI ET AL.

Examiner

Irina S. Zemel

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 1004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 1, 2, 12 and 13 are objected to because of the following informalities:

Claims 1 and 2 recite various substituents corresponding to R, R1 and X. Those substituents should be listed in the alternative. Claim 12 recited "oligomers" in plural, while the base claim recites "oligomer". Claim 13 recites "monomer NAG", while the base claim recites "monomeric NAG". Appropriate correction is required for consistency purposes.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Steps of production of polymers/oligomers are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The invention as claimed encompasses various oligomers containing various X groups. However, the only group that is specifically discussed so far as preparing corresponding oligomers is N-AcetylGlucoseamine (NAG). The specification and claims 2 expressly state that the method of preparing any of the claimed oligomers involves the step of "dissolving (polymerizable) monomeric NAG...". However,

dissolving polymerizable monomeric NAG such as (M)Ac.NAG and polymerizing it does NOT result in oligomers having any X substituent other than NAG. A method for obtaining homopolymers corresponding to the formula (1) with any other substituent group X is not disclosed anywhere in the specification. It is not clear how the claimed homopolymers can be obtained by a process that involves polymerization of polymerizable NAG. The claimed invention is clearly directed to a homopolymer, i.e. a polymerized compound that contains *identical* monomeric units. It logically appears that a homopolymer that contains X unit other than NAG, and which is obtained by a process including the step of dissolving and polymerizing polymerizable NAG monomers can only be obtained by some post-polymerization modification of polymerized (M)Ac.NAG. No such steps or directions for such modification is disclosed in the specification. No other methods of obtaining homopolymers containing other X groups are disclosed in the specification. No starting materials, no reaction conditions, etc., that lead to preparation of the claimed oligomers with various (other than NAG) X groups is disclosed in the specification. Furthermore, the claims are directed to homopolymers and do not encompass co-polymers, as evident either from the formula or the description of X substituent. A process of obtaining co-polymers that may contain other monomeric units with other X substituents that can be, conceivably, obtained by the step that involve reaction polymerizable monomeric NAG (with other co-monomers) is outside of the scope of the claimed invention.

Therefore, the essential material, i.e., a method of obtaining claimed polymers other than NAG containing homopolymers is not enabled by the disclosure.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The invention as claimed is drawn to a process for preparation of various oligomers containing various X groups. The process of claim 2 comprises a step of "dissolving a monomeric NAG in a solvent and adding a chain terminating agent...". The following aspect of the claim is unclear and confusing:

1. There is no definition of abbreviation NAG appearing on sixth line from the bottom of claim 2. In this abbreviation correspond to N-acetylglycosamine (as disclosed in the specification), then, it is not understood how using monomeric NAG results in the oligomers of the Formula (1), since the monomeric unit of the claimed oligomer is not a NAG, but a monomeri such as (mth)acrylol unit having NAG as a substituent (which is described in the specification as *polymerizable* monomeric NAG). The oligomerization (or polymerization) reaction of the monomers does not involve NAG substituent and takes place via ethylenic unsaturation of acrylic or other reactive group. Applicants should define the claimed subject matter to avoid any confusion and uncertainties.

2. Even if, arguendo, the claim language monomeric "NAG" is given an interpretation of N-Acetyl Glucosamine (meth)acrylol (which contradicts the definition of NAG in the specification), or polymerizable monomeric NAG, it is understood how a polymer having any X substituents other than N-Acetyl Glucoseamine can be obtained by the recited steps which expressly include a step of "dissolving a monomeric NAG in a solvent..."

Claims 3, 4, and 6 recites the limitation "the monomer", "said monomer", and "monomeric ligand". There is insufficient antecedent basis for this limitation in the claims. Although claim 2 recites "monomeric NAG", it is not clear whether this recitation correspond to the recitations in claims 3,4 and 6.

Claim 10 recites the limitation "saidcarbohydrate ligand" in line 1 ("saidcarbohydrate" in one word). There is insufficient antecedent basis for this limitation in the claim.

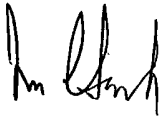
To the extent that the claimed subject matter is limited to the polyfunctional oligomers of formula (1) with X=NAG and the process of forming corresponding oligomers (X=NAG), the prior art of record does not disclose homopolymers (oligomers) containing monomeric units corresponding to polymerized compounds of formula (2). Both US Patent 6,605,714 and article by Vaidya disclose copolymers having minor amount of monomeric units corresponding to the unit of formula (2) and major amount of other (acryl amide) co-monomers. Both references further teach away from increasing the amount of monomeric units corresponding to formula (2) by disclosing low effectiveness of NAG containing units in binding and inhibition of biomolecules.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irina S. Zemel whose telephone number is (571)272-0577. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571)272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ISZ



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